DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 12, 2015

Pelvalon, Inc.
% Cindy Domecus
Principal
Domecus Consulting Services LLC
1171 Barroilhet Dr
Hillsborough, CA 94010

Re: K150558
Trade/Device Name: Eclipse System
Regulation Number: 21 CFR 876.5930
Regulation Name: Rectal Control System
Regulatory Class: II
Product Code: PJH
Dated: November 2, 2015
Received: November 3, 2015

Dear Cindy Domecus,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT (FORM FDA 3881)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
~~Unknown~~ K150558

Device Name
Eclipse System

Indications for Use *(Describe)*
The Eclipse System is indicated for treatment of fecal incontinence in adult women.

It is intended for prescription use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

A. Submitter

Company Name:	Pelvalon, Inc.
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Contact Fax:	650-343-7822
Contact e-mail:	domecusconsulting@comcast.net
Date Prepared:	February 27, 2015

B. Device

Name of Device:	Eclipse System
Model Number:	4.1
Common Name:	Rectal Control System
Classification Name:	21 CFR 876.5930
Regulatory Class:	II
Product Code:	PJH

C. Predicate Device

DEN140020	Eclipse System, 3.2
	The predicate device has not been subject to a design-related recall.
	No reference devices were used in this submission.

510(k) Summary

D. Device Description

Eclipse System Components

The Eclipse System includes two main components, an Insert and a Pump. The Insert is used intra-vaginally, is insertable/removable by the patient, and includes a balloon that when inflated, exerts a force posteriorly (trans-vaginally) against the wall in the rectum resulting in a decrease in the lumen of the rectum. The compression of the rectal space results in decreased frequency of fecal incontinence events. The Eclipse System also contains two tools for the fitting process: a Sizing Kit, consisting of Sizers in each available Insert Base size, and a Trial Insert. Each component is described below.

- **Sizing Kit / Sizers:** Reusable (multi-patient) Insert Bases (Sizers), intended to aid in selecting appropriate Trial Insert Sizes. Sizers are only used in a clinical setting (<60 minutes) and are not intended to be taken home.
- **Trial Insert (Insert)**: Single-patient-use vaginal insert intended for short term use (approximately 1 week, but no more than 2 weeks) during the fitting and evaluation process. Multiple Trial Inserts may be attempted to achieve a correct fit. The Trial Inserts are identifiable by their white color.
- **Eclipse Insert (Insert)**: Single-patient-use vaginal insert intended for longer-term use (up to 1 year). The Eclipse Inserts are identifiable by their indigo color.
- **Pump, including Regulator:** The pump is used by the patient for inflating and deflating the balloon with a goal of improving control over bowel movements. The Pump includes a replaceable Regulator which regulates the maximum pressure of the Insert's Balloon. Regulators are available for different pressure levels, and can be replaced to adjust the maximum pressure of the Insert's Balloon.

E. Intended Use/Indications for Use

The Eclipse System is indicated for the treatment of fecal incontinence in adult women. It is intended for prescription use. The indications for use are unchanged from the predicate.

F. Comparison of Technological Characteristics with the Predicate Device

The Eclipse System has the same fundamental scientific technology as the predicate device and is substantially equivalent to the predicate device with respect to design, materials, and intended use.

510(k) Summary

Key similarities of the Eclipse System to the predicate device are as follows:

- System Components:
  - The Eclipse System of the subject device includes the Eclipse Insert, which is identical to the Eclipse Insert of the predicate device with respect to geometry, dimensions, and use.
  - The Eclipse System of the subject device includes the Pump, which is identical to the Pump of the predicate device.
- Design/Materials:
  - The Eclipse Insert of the subject device shares the same geometry and dimensions as the Eclipse Insert of the predicate device and is manufactured from the same material families, and many identical materials.
  - The Trial Insert of the subject device shares the same geometry, dimensions, and surface material families as the Eclipse Insert of the predicate device.
  - The Sizers that comprise the Sizing Kit of the subject device share the same base dimensions and are manufactured from the same materials families as the Eclipse Insert of the predicate device.
- Use:
  - The fitting procedure for the subject device is similar to the process used for the predicate device.
  - The patient interacts with the Inserts of the subject device in an identical fashion as the predicate device.
- Cleaning and Disinfection:
  - The cleaning process/instructions for the Eclipse Insert, Trial Insert, and Sizer of the subject device are identical to the predicate device.
  - The disinfection process/instructions for the Eclipse Insert and Trial Insert of the subject device are identical to the predicate device.
- Packaging:
  - The packaging used for the Sizer, Trial Insert, and Eclipse Insert of the subject device is identical to that of the predicate device

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510(k) Summary

Key differences of the Eclipse System from the predicate device are as follows:

- System Components:
  - In addition to the Eclipse Insert and Pump, which were present in the predicate device, the subject device also contains two tools for the fitting process: a Sizing Kit (Sizers) and a Trial Insert.
- Design/Materials:
  - The Eclipse Insert, Trial Insert, and Sizer of the subject device utilize additional pigments to color the silicone for ease of identification.
  - The short term use Trial Insert of the subject device uses a different internal support material than the predicate device Eclipse Insert.
- Use:
  - Sizing Kits (Sizers) of the subject device are used to aid in selecting appropriate Trial Insert Sizes. They are re-useable and require high-level disinfection.
  - The Trial Insert of the subject device is provided for short-term use to aid in confirmation of fit before longer term use of the Eclipse Insert.
- Cleaning and Disinfection:
  - The Sizers of the subject device are re-usable and require high-level disinfection between uses. A high-level disinfection process/instructions and alternative steam sterilization validation process/instructions were validated
- Packaging:
  - There are no differences in packaging between the subject device and the predicate device

G. Performance Data

The following performance data were provided in support of substantial equivalence:

- Bench Testing
  - Dimensional/Visual Inspections
  - Leak Testing
  - Cycle Testing
  - Inflation/Deflation Testing
  - Valve-Pump Attachments

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510(k) Summary

  - Tube Stretch
  - Base Folding
  - Basic Function/Performance
- Biocompatibility Testing per ISO 10993-1
- High Level Disinfection Validation
- Steam Sterilization Validation (as an alternative to high-level disinfection)

Cleaning and Low Level Disinfection validations performed on the predicate device support the cleaning and low level disinfection instructions for the Eclipse Insert, Pump, and Trial Insert that are the subject of this 510(k). No additional cleaning/low level disinfection testing was required to support substantial equivalence.

The clinical performance data submitted in support of the de novo application for the predicate device are sufficient to address safety and effectiveness of the subject device. The modifications to the predicate device that are the subject of this 510(k) application are not significant enough to require clinical performance data to demonstrate substantial equivalence.

The Eclipse System met all specified design, safety, and performance requirements. Collectively the performance data support safety, effectiveness, and substantial equivalence of the Eclipse System to the predicate device.

H. Conclusions

The information and data provided in the 510(k) demonstrate that the subject Eclipse System is as safe and effective and substantially equivalent to the predicate Eclipse System.